

REV AUTHORED BY <b>G. UYEKI</b>	DATE <b>4/21/2021</b>			 SIGNATURES ON FILE	
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PROPRIETARY: This document contains proprietary data of Hologic, Inc. No disclosure, reproduction or use of any part thereof may be made except by written permission from Hologic.		TITLE <b>IFU, RAPID FFN CONTROL TEST KIT, OUS, EN</b>	DOCUMENT NUMBER <b>AW-29351-001</b>	REV <b>002</b>	
REV. RELEASE DATE:	05/14/2021		SIZE A	SHEET 1 OF 1	

## To be used by trained medical personnel only.

The Hologic Rapid fFN Control Kit is for use with the Rapid fFN<sup>®</sup> Tests (PeriLynx<sup>™</sup> system, Rapid fFN<sup>®</sup> 10Q system).

### INTENDED USE

The Rapid fFN Control Kit, consisting of the Negative/Level 1 Control and the Positive/Level 2 Control, is intended to be used to monitor the performance of the Rapid fFN<sup>®</sup> 10Q cassettes with the PeriLynx<sup>™</sup> analyzer and the Rapid fFN<sup>®</sup> 10Q analyzer.

### PRECAUTIONS AND WARNINGS

- For *in vitro* diagnostic use only.
- Source material used to prepare the controls is of human origin. The donors were tested and found to be negative for HIV 1, HIV 2, and HCV antibody and hepatitis B surface antigen (HBsAg) using established methods. No known test method can offer total assurance that HIV, hepatitis C virus, hepatitis B virus, or other infectious agents are absent. **Handle these reagents and all patient specimens as if potentially infectious.**
- Do not use glass tubes or glass pipettes, as fetal fibronectin (fFN) binds to glass. Tubes and pipettes of polypropylene or polyethylene are acceptable.**
- Reagents in this kit contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. Thus, when disposing of the reagents, always flush the drain with large volumes of water to prevent azide build-up.
- Do not use controls beyond the expiration date printed on the bottle.
- Do not use controls if they are cloudy or discolored, or if the bottles have leaked.
- Avoid cross-contamination of reagents. Use a new pipette for each control or patient sample. Recap reagents tightly with the correct color-coded caps.

### STORAGE AND STABILITY

Store the Rapid fFN Control Kit at 2° to 8°C. The shelf life of the Rapid fFN Control Kit is one year from the date of manufacture. Unopened controls may be used until the expiration date printed on the bottle. Once opened, they should be used within 6 months.

### MATERIALS PROVIDED

- Rapid fFN Negative/Level 1 Control: One bottle containing 2.5 mL human fetal fibronectin (<50 ng/mL) in a stable protein matrix with sodium azide as a preservative. Store at 2° to 8°C. Use at room temperature.
- Rapid fFN Positive/Level 2 Control: One bottle containing 2.5 mL human fetal fibronectin (>50 ng/mL) in a stable protein matrix with sodium azide as a preservative. Store at 2° to 8°C. Use at room temperature.
- Directional Insert

**Note:** Quantitative fFN assay results are reported in units of ng/mL and the result is standardized using purified fFN and A280 measurement with a  $\epsilon = 1.28$ .<sup>1</sup>

### PROCEDURE FOR PERILYNX SYSTEM AND RAPID FFN 10Q SYSTEM

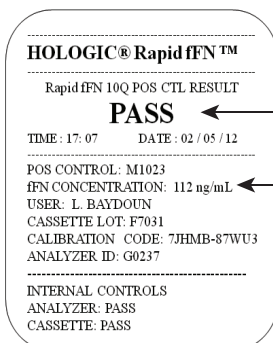
- Allow control solutions to come to room temperature before testing.
- Remove one Rapid fFN 10Q Cassette from the foil pouch.
- Select **Run Liquid QC** on the PeriLynx analyzer, or **8 – LIQUID CONTROLS** from the Rapid fFN 10Q analyzer Main Menu and enter the necessary information until the analyzer prompts for cassette insertion.
- Insert the cassette into the analyzer and press **Next** or **ENTER**.
- When prompted by the analyzer, pipette 200  $\mu$ L of control solution into the sample application well of the Rapid fFN 10Q Cassette. Immediately press **Start Test** or **ENTER** to activate the analyzer.
- The analyzer will begin a countdown, with 7 minutes of incubation and 2–3 minutes of analysis of the cassette.
- The fFN concentration result for the control will be displayed on the analyzer display screen.

**Recommended frequency of use is one Negative/Level 1 Control and one Positive/Level 2 Control each time a new lot or a new shipment of cassettes is received, or whenever there is uncertainty about the cassettes.** The control testing may be performed more frequently, in accordance with your local applicable requirements. Deviation from the recommended frequency of quality control testing must be validated by the laboratory.

1 Yamada KM. "Fibronectin and Other Structural Proteins." in *Cell Biology of Extracellular Matrix*, Ed ED Hay. 1st ed. New York: Plenum Press, 1981. 95-114.

### EARLIER SOFTWARE VERSION (1.0) OF THE RAPID FFN 10Q ANALYZER

Acceptable results for the Negative/Level 1 and Positive/Level 2 Controls will be displayed on the Rapid fFN 10Q Analyzer as **PASS** **AND** the fFN concentration results should fall within the expected values provided on the control kit box. Retest out-of-range controls, **FAIL** or **INVALID** control results. Do not test patient samples until acceptable results are obtained with the controls. If the problem continues, please call Hologic for technical assistance.



**NOTE:** Acceptable results for the Negative/Level 1 and Positive/Level 2 Controls will be displayed on the Rapid fFN 10Q Analyzer as **PASS** **and** the fFN concentration results **should** fall within the expected values in this kit.

### TECHNICAL SUPPORT AND ORDERING INFORMATION

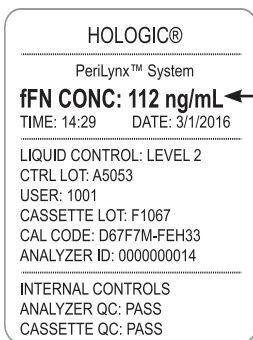
USA/CANADA ONLY Tel: 1-800-442-9892  
 Fax: 1-508-229-2795

ALL OTHER COUNTRIES Contact your local Hologic representative or call:  
 Tel: 00800 800 29892  
 Fax: +41 (0) 21 633 39 10

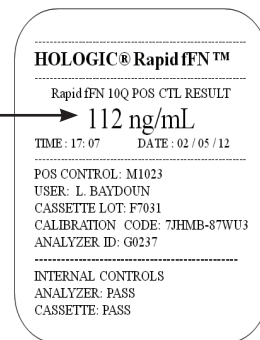
For additional contact information, go to [www.ffntest.com](http://www.ffntest.com)

### EXPECTED RESULTS FOR PERILYNX SYSTEM AND RAPID FFN 10Q SYSTEM

Refer to the expected values printed on the control kit box. The expected values are derived from data using multiple Hologic analyzers and Rapid fFN 10Q Cassette lots and are specific to this lot of controls. Confirm that the lot numbers on the control bottles correspond to the lot numbers on the control box label. The fFN concentration result for the Negative/Level 1 and the Positive/Level 2 Controls should fall within the expected values. Retest out-of-range controls or an **INVALID** control result. Do not test patient samples until acceptable results are obtained with the controls. If the problem continues, please call Hologic for technical assistance.



**NOTE:** Acceptable results for the Negative/Level 1 and Positive/Level 2 Controls **should** have fFN concentration results fall within the expected ranges provided on the control kit box.



Authorized Representative in the European Community



Catalogue Number



Mean



Batch code



*In Vitro* Diagnostic Medical Device



Range



Biological Risks



Negative/Level 1 Control



Temperature limitation: 2°–8°C



Consult instructions for use



Positive/Level 2 Control



Use by



Manufacturer